No. 640

In the Supreme Court of the United States

OCTOBER TERM, 1948

UNITED STATES OF AMERICA, PETITIONER

v.

FRED URBUTEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELLED "SINUTHERMIC", ETC.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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The Solicitor General, on behalf of the United States, prays (1) that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Fifth Circuit reversing the judgment of the United States District Court for the Northern District of Florida condemning certain devices as misbranded under Section 304 of the Federal Food, Drug, and Cosmetic Act, and remanding the case to the District Court for further proceedings in conformity with the earlier opinion of this Court (No 13, this Term, 335 U. S. 355) and

the opinion of the Court of Appeals, and (2) that the judgment of the Court of Appeals be reversed and the cause remanded to it with directions to consider the question whether the Government is entitled to a decree of condemnation by reason of the false and misleading character of the advertising matter involved in this case as respects the diagnostic capabilities of the devices.

OPINIONS

The opinion of the Court of Appeals on the remand of the cause by this Court (R. 6-7) is not yet reported. The earlier opinion of the Court of Appeals (No. 13, this term, R. 179-183) is reported at 164 F. 2d 245. The opinion of this Court reversing the earlier judgment of the Court of Appeals is reported at 335 U.S. 355.

JURISDICTION

The judgment of the Court of Appeals was entered February 1, 1949 (R. 7). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the Court of Appeals violated the mandate of this Court in *United States* v. *Urbuteit*, 335 U.S. 355, in remanding the case to the District Court with directions to retry the question whether there was a single interrelated activity in the interstate movements of the machines and advertising matter involved as to each such shipment or any of them.

2. Whether the Court of Appeals complied with the mandate of this Court in failing to consider whether the Government is entitled to a decree of condemnation because of the false character of the advertising matter as respects the diagnostic capabilities of the devices.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U.S.C. 301 *et seq.*), provides in pertinent part:

SEC. 201. For the purposes of this Act—

* * *

(h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; * * *.

* * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court

of the United States within the jurisdiction of which the article is found. * * *

SEC. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

STATEMENT

On January 9, 1947, a second amended libel of information was filed in the United States District Court for the Northern District of Florida, under Section 304 of the Federal Food, Drug, and Cosmetic Act, seeking the seizure and condemnation of 16 articles of device labeled "Sinuothermic" (No. 13, R. 11-15). The libel alleged that the devices were misbranded within the meaning of Section 502(a) of the Act when introduced into and while in interstate commerce in that representations made in leaflets entitled "The Road to Health", relative to the curative and therapeutic powers of the device in the diagnosis, cure, mitigation, treatment, and prevention of disease, were false and misleading. It was charged that the leaflets, which had been shipped physically apart from the devices, had accompanied the devices in interstate commerce so as to constitute "labeling" under the definition of that term contained in Section 201 (m) of the Act.

In addition to many representations of curative value involving, among many others (see No. 13, R. 165), such various diseases as cancer, tuberculosis, diabetes, and heart disease, the leaflet, "The

Road to Health" represented that the machines were capable of diagnosing the cause of any ailment.[1] The Government's evidence showed that the device was without value in the diagnosis of the disease conditions indicated (No. 13, R. 72, 76, 79-80, 83-85, 88-89, 94, 93, 96-97, 99, 100, 104-105, 109-112), and respondent Urbuteit admitted that the device alone was incapable of diagnosing disease (No. 13, R. 129-130).

The trial court found, *inter alia*, that the leaflets had accompanied the devices while in interstate commerce (No. 13, R. 164); that the leaflets claimed diagnostic values and therapeutic effects for the machines in many conditions (No. 13, R. 165, Finding 4); that the master model was incapable of diagnosing disease (No. 13, R. 165-166, Finding 5); and that the claims of therapeutic and curative effect were false and misleading (No. 13, R. 166). Accordingly, the court entered a decree condemning the devices (No. 13, R. 168-169).

On appeal, the court below reversed the judgment and remanded the cause for further proceedings on the grounds (1) that since the leaflets had been shipped apart from the devices, they did not accompany them while in interstate commerce and hence did not constitute labeling within the meaning of the Act, and (2) that the trial court erred in excluding certain testimony offered by respond-

[1] The leaflet is not reproduced in the record in No. 13, but copies are on file with the Clerk. See the excerpts from the leaflet quoted in our brief in No. 13, pp. 6-7.

ent as to the curative value of the devices (No. 13, R. 179-183; 164 F. 2d 245).

Thereafter, on petition by the Government, this Court granted certiorari (333 U. S. 872) and heard the case together with the companion case of *Kordel* v. *United States* (No. 30, this Term, 335 U. S. 345). The Government urged that the relationship of the leaflets to the devices was such that they constituted labeling within the meaning of Section 201(m) of the Act. The Government also contended that even if it were assumed that the District Court erred in excluding the proffered evidence relating to the curative value of the machines, the Government was entitled to a decree of condemnation (if it prevailed on the "accompaniment" issue), since it appeared from the undisputed testimony and from respondent's own admissions that the machines did not possess the diagnostic capabilities claimed for them. This Court held that the leaflets did accompany the devices so as to constitute labeling under the Act, saying that "In this case it is plain to us that the movements of machines and leaflets in interstate commerce were a single interrelated activity, not separate or isolated ones" (335 U. S. at 357). In reversing the judgment of the Court of Appeals, this Court did not disturb the ruling below that the District Court was wrong in excluding respondent's proffered testimony, and the Court said that "since the cause must therefore be remanded to the

Court of Appeals, the question whether the Government was entitled to a decree of condemnation because of the falsity of the claims made in the leaflets in respect of the diagnostic capabilities of the devices would be open for consideration by that court, together with any other questions that had survived.

On the remand, the Government filed a motion in the Court of Appeals to affirm the decree of condemnation, urging, as we did here (see our brief in No. 13, pp. 37-41), that error in excluding the testimony relating to curative properties of the device did not affect the Government's right to such a decree on the basis of the undisputed evidence of misbranding in falsifying its value in diagnosing diseases (R. 1-6). The Court of Appeals did not consider this contention. Instead, it construed the opinion of this Court as holding merely that "certain advertising matter shipped separately from any of the machines and held by us for that reason not to have 'accompanied' any of them *might* nevertheless constitute 'labeling,' *if* the movements of advertising and machines in interstate commerce were a single interrelated activity and not separate or insolated ones." (Italics supplied.) After adverting to the fact that there were several shipments of the devices and only one shipment of the leaflets, the court below said: "It does not appear whether there was a single interrelated activity in machines and advertising as

to each shipment, or as to which shipments. That appears to be a question which should be further investigated." The court adhered to its earlier ruling that the trial court erred in excluding respondent's proffered testimony referred to above, and concluded that the judgment should be reversed and the cause remanded to the District Court "for further proceedings in conformity with the opinion of the Supreme Court and with this opinion." (R. 6-7.)

SPECIFICATION OF ERRORS TO BE URGED

The Court of Appeals erred:

1. In remanding the case to the district court with directions to retry the question whether there was a single interrelated activity in the interstate movements of the machines and advertising matter as to each shipment of the machines or any of them.

2. In failing to consider whether the Government was entitled to a decree of condemnation by reason of the falsity of the diagnostic claims made for the devices, notwithstanding the error of the district court in excluding respondent's proffered evidence relating to their curative value.

REASONS FOR GRANTING THE WRIT

It is apparent, we think, that the Court of Appeals has failed to comply with the mandate of this Court in two respects.

First. The principal issue before this Court when the case was here earlier this term was whether the leaflets "accompanied" the devices and so constituted "labeling" within the meaning of Section 201(m) of the Act. The District Court held that they did, but this holding was reversed by the Court of Appeals. In reversing the judgment of the Court of Appeals, this Court said that although the leaflets were shipped separately from the machines—

> * * * It was the leaflets that explained the usefulness of the device in the diagnosis, treatment, and cure of various diseases. Measured by functional standards, as § 201 (m) (2) of the Act permits, these leaflets constituted one of the types of labeling which the Act condemns.
>
> The power to condemn is contained in § 304 (a) and is confined to articles "adulterated or misbranded when introduced into or while in interstate commerce." We do not, however, read that provision as requiring the advertising matter to travel with the machine. The reasons of policy which argue against that in the case of criminal prosecutions under § 303 are equally forcible when we come to libels under § 304 (a). Moreover, the common sense of the matter is to view the interstate transaction in its entirety—the purpose of the advertising and its actual use. *In this case it is plain to us that the movements of machines and leaflets in interstate commerce were a*

single interrelated activity, not separate or isolated ones. [335 U. S. at 357; italics supplied.]

Notwithstanding this clear holding, the Court of Appeals interpreted this Court's opinion as meaning merely that it was wrong as a matter of law in its view that a separate shipment of advertising matter could not constitute labeling; and that in this case the leaflets "might" have been labeling "*if* the movements of advertising and machines in interstate commerce were a single interrelated activity and not separate or isolated ones" (R. 6; italics supplied). The Court of Appeals thought that this question "should be further investigated" (*ibid.*) and accordingly reversed the judgment of the District Court and remanded the case with directions which in effect require a retrial of the issue. But that issue was resolved by the holding of this Court that the leaflets did accompany the machines involved in this proceeding and did constitute labeling within the meaning of the Act. Manifestly, the District Court cannot comply with both the opinion of this Court and the opinion of the Court of Appeals. We think it is clear, therefore, that the judgment of the Court of Appeals must be reversed with directions to abide the decision of this Court on this issue.

Second. The Court of Appeals has also failed to comply with the mandate of this Court in an-

other important respect. As we have pointed out, the Government contended before this Court that it was entitled to a decree of condemnation even if the Court of Appeals was correct in holding that respondent's proffered evidence as to the curative properties of the devices was improperly excluded by the District Court, since it appeared from undisputed evidence and from the admissions of respondent himself that the devices did not possess the diagnostic capabilities claimed for them in the leaflets. This Court said that it was not inclined to disturb the Court of Appeals' ruling on the admissibility of respondent's evidence and that since the case must therefore be remanded to the Court of Appeals, the issue raised by the Government's contention "will be open for consideration by it." (335 U. S. at 358.)

The Court of Appeals, however, did not consider the Government's contention; instead, it merely expressed adherence to its earlier ruling that the testimony offered by respondent should have been admitted (R. 7). We submit that under this Court's mandate the Government is entitled to a decision on the question whether the devices are subject to condemnation on the basis of the false claims in respect of their diagnostic value. If that question, the only one surviving in the case, is decided favorably to the Government, the decision will terminate the litigation and, if not, such ques-

tions as remain will be clarified for the guidance of the District Court.

CONCLUSION

For the reasons stated, we respectfully submit that this petition should be granted and that the judgment of the Court of Appeals should be reversed and the case remanded to it with appropriate directions in accordance with the earlier opinion of this Court. Since the issues presented involve only the correct construction of this Court's mandate, we respectfully suggest that, subject to respondent's right to file an opposing brief, the case may properly be disposed of without further briefs or argument.

Respectfully submitted.

PHILIP B. PERLMAN,
Solicitor General.

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